ONE HUNDRED NINTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM
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October 21, 2005

Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

In February of this year, the Committee on Government Reform began conducting an investigation into the use of illegal performance-enhancing drugs in major league sports. This investigation was initiated in large part due to my ongoing concern regarding the use of steroids among youth. The Committee held hearings on steroid use and the testing policies for professional baseball, football, and basketball, as well as the use of steroids among women. I am also personally involved in the Advisory Committee on Ending the Use of Performance-Enhancing Drugs in Sports, commonly known as "Zero Tolerance." The main focus of Zero Tolerance is the eradication of steroid use among youth, including drug education and examining how to keep illegal performance-enhancing drugs out of the hands of young people.

Therefore, I read with much interest the October 18, 2005, *Washington Post* article entitled "Chemists Stay a Step Ahead of Drug Testers." In preparation for the article, the newspaper purchased five dietary supplements, all of which were labeled as muscle building supplements and were available over the Internet. The supplements were tested by the University of California, Los Angeles Olympic Analytical Laboratory ("UCLA Olympic Lab") for anabolic steroids. All five tested positive for what are commonly known as "designer steroids," including four steroids for which there was previously no test.

In addition, the Director of the UCLA Olympic Lab noted that none of the five bottles contained labels identifying the substance as a dietary supplement, as required by the Dietary Supplement Health and Education Act of 1994 (DSHEA) - raising questions as to whether the Food and Drug Administration (FDA) is fulfilling its oversight responsibility regarding the proper labeling of dietary supplements.

The public needs to be assured of the safety of dietary supplement products and the reliability of their labeling. While FDA does not approve dietary supplements for safety and effectiveness, FDA still has the responsibility to ensure that manufacturers do not mislead the consumer about dietary supplement contents. With the five dietary supplements tested in the previously mentioned *Washington Post* article, consumers could not know that they contained anabolic steroids.

In light of the Committee's concern regarding the use of steroids among adolescents, and the apparent increase in designer steroid production and use, we are requesting that you provide the Committee with the information requested below by November 7, 2005:

1. What specific steps is FDA taking to ensure that dietary supplements found to contain anabolic steroids are not available for purchase by consumers?

2. How does FDA work with law enforcement officials when FDA discovers companies that are manufacturing dietary supplements containing illegal steroids?

3. Has FDA received complaints through the MedWatch adverse event reporting system of illnesses or injuries due to dietary supplements containing anabolic steroids?

    a. If so, please provide a list of the types of illnesses and injuries reported and the correlating dietary supplement linked to each illness or injury.

    b. Please also provide the specific action taken by FDA for each reported illness or injury to ensure the dietary supplement in question was not unsafe and did not contain anabolic steroids.

4. FDA states that as part of its oversight of dietary supplements, some resources are devoted to the "routine monitoring of products pulled from store shelves or collected during inspections of manufacturing firms." Does part of this routine monitoring include testing dietary supplements for anabolic steroids, including designer steroids? If so, provide a list of each such test and the results, from 2000 to present.

5. As mandated by DSHEA, dietary supplement manufacturers are required to label their product with a descriptive name of the product stating that it is a "supplement;" the name and place of business of the manufacturer, packer, or distributor; a complete list of ingredients; and the net contents of the product.

    a. How does FDA monitor the labeling of dietary supplements to ensure the DSHEA labeling requirements are followed?

b. What are the consequences for a manufacturer, packer, or distributor whose dietary supplement products do not contain the DSHEA labeling requirements?

6. What is the Current Good Manufacturing Process (cGMP) for dietary supplement manufacturers?

   a. If there is there is no cGMP in place, on what date will FDA begin implementation of cGMP for dietary supplement manufacturers, including inspection and enforcement?

   b. What will the consequences be for dietary supplement manufacturers whose products contain anabolic steroids if they are in violation of the cGMP?

7. With regard to the five dietary supplements discussed in the *Washington Post* article, Applied Lifescience Research Industries' (ALRI) Ergomax LMG, Anabolic Xtreme's Superdrol, ALRI's Prostanozol, PharmGenX FiniGenX Magnum Liquid, and Legal Gear's Methyl 1-P, provide the following information:

   a. Whether any of these supplements contain a "new dietary ingredient," and if so, provide

      1. notification to FDA of intention to market the dietary supplement in the U.S.;

      2. all documentation demonstrating the safety of the ingredient for use in a dietary supplement;

   b. Documentation that the dietary ingredients were marketed before October 15, 1994;

   c. Any MedWatch claims of adverse events or illness;

   d. All enforcement actions against the manufacturers for either the dietary supplement listed above, or for any dietary supplement they have manufactured; and

   e. FDA's plans to review these products for potential improper labeling, safety of the supplement, and presence of anabolic steroids.

If you have any questions regarding this request, please contact [redacted] at (202) 225-5074. In addition, I ask that you make your staff available to brief Committee staff on these issues at such time that is requested.

Sincerely,

Tom Davis
Chairman

cc: Henry A. Waxman, Ranking Member